

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al.	:	
ex rel. FRANK SMITH,	:	
	:	
Plaintiffs	:	
	:	
v.	:	Civil Action No. 10-cv-0999
	:	
ASTELLAS PHARMA US, INC., et al.	:	
	:	
Defendants	:	

JOINT STIPULATION OF DISMISSAL

The United States of America and Relator Frank Smith, through counsel, and pursuant to Rule 41(a)(1)(A)(i) of the Federal Rules of Civil Procedure and the Settlement Agreement executed by the United States, Relator Frank Smith, and Defendant Astellas Pharma US, Inc., file this Joint Stipulation of Dismissal as to the Defendants.

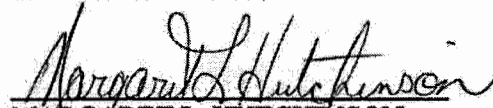
In accordance with Paragraph 16 of the Settlement Agreement and under Rule 41(a)(1)(B) of the Federal Rules of Civil Procedure, the dismissal shall be as follows:

- (1) with prejudice to the United States as to the Covered Conduct as defined in Recital Paragraph F of the Settlement Agreement, attached hereto as Exhibit 1;
 - (2) without prejudice to the United States as to all other claims; and
 - (3) with prejudice to the Relator as to all claims under the Federal False Claims Act.
- Relator anticipates filing a stipulation of dismissal as to the states in accordance with their separate settlement agreement.


Respectfully submitted,

ZANE DAVID MEMEGER
United States Attorney

Dated: 4/16/2014

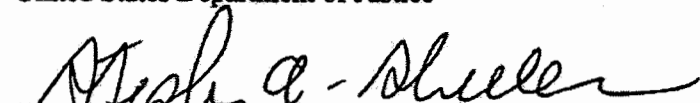

MARGARET L. HUTCHINSON
Assistant United States Attorney
Chief, Civil Division

Dated: 4/16/2014


SUSAN R. BECKER
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street Suite 1250
Philadelphia, PA 19106

MICHAEL D. GRANSTON
JAMIE A. YAVELBERG
CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Dated: 4/15/14


STEPHEN A. SELLER
Sheller, P.C.
1528 Walnut Street, Floor 3
Philadelphia, PA 19102
Counsel for Relator Frank Smith

SO ORDERED: April 17, 2014

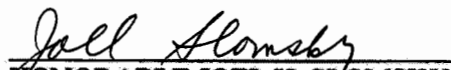

HONORABLE JOEL H. SLOMSKY
Judge, United States District Court

EXHIBIT 1

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) and the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP) (collectively the "United States"); Astellas Pharma US, Inc. ("Defendant"); and Frank Smith ("Relator") (all collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Astellas Pharma US, Inc. is a pharmaceutical company based in Northbrook, Illinois. Astellas Pharma US, Inc. is an indirect subsidiary of its affiliate, Astellas Pharma Inc., based in Tokyo, Japan. At all relevant times, Astellas Pharma US, Inc. distributed, marketed, and sold pharmaceutical products in the United States, including Mycamine® (NDC Nos. 00469321110, 00469325010).

B. Mycamine® is a sterile, lyophilized antifungal agent that contains micafungin sodium and is administered through intravenous infusion. In 2005, Mycamine® was approved to treat adult patients with esophageal candidiasis and for prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantations. In 2008, Mycamine® was also approved to treat adult patients with Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses. From 2005 to June 23, 2013, Mycamine® was not approved to treat pediatric patients for any use.

C. On March 8, 2010, Relator filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Frank Smith, et al. v. Astellas Pharma US, Inc., et al.*, Civil No. 10-999, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator filed his Third Amended Complaint on November 21, 2012.

D. Defendant has entered or will enter into separate settlement agreements, described in Paragraph 1(b) below (“Medicaid State Settlement Agreements”), with certain states (“Medicaid Participating States”) in settlement of the Covered Conduct described below.

E. The United States contends that Defendant submitted or caused to be submitted claims for payment to the Medicaid Program (Medicaid), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5; and the FEHBP, 5 U.S.C. §§ 8901-8914.

F. The United States contends that it and the Medicaid Participating States have certain civil claims against Defendant arising from the marketing, promotion, and sale of Mycamine® between January 1, 2005 through December 31, 2010 as follows (referred to throughout this agreement as the “Covered Conduct”): Defendant knowingly marketed and promoted the sale and use of Mycamine® for pediatric patients, when the drug had not been approved as safe and effective by the Food and Drug Administration (“FDA”) for such patients, and such use was not a medically-accepted indication as defined by 42 U.S.C. 1396r-8(k)(6), and the United States and State Medicaid programs did not provide coverage for such use of Mycamine®. The United States contends that as

a result of this conduct the Defendant knowingly caused false or fraudulent claims for Mycamine® to be submitted to Medicaid and FEHBP.

G. This Settlement Agreement is neither an admission of liability by Defendant nor a concession by the United States that its claims are not well founded. Defendant expressly denies the allegations of the United States and Relator as set forth herein and in the Civil Action.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendant shall pay to the United States and Medicaid Participating States seven million, three hundred thousand dollars (\$7,300,000) (the "Settlement Amount") and interest on the Settlement Amount at a rate of 1.25% from December 18, 2013 to and including the day payment is made under this Agreement as described in Paragraphs 1(a) and 1(b) below. The Settlement Amount shall be discharged by payments to the United States and the Medicaid Participating States subject to the following terms and conditions:

a. Defendant shall pay to the United States the sum of \$4,169,723.50 plus interest as set forth above ("Federal Settlement Amount") no later than five business days after the Effective Date of this Agreement by electronic funds

transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Eastern District of Pennsylvania;

b. Defendant shall pay to the Medicaid Participating States the sum of \$3,130,276.50 plus interest as set forth above ("State Settlement Amount") subject to the terms and conditions of the Medicaid State Settlement Agreements between Defendant and the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Defendant and as soon as feasible after receipt, the United States shall pay \$708,852 to Relator by electronic funds transfer.

3. Relator acknowledges receipt of Defendant's full and complete payment of Relator's attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) incurred in connection with the Civil Action. No additional attorneys' fees or costs shall be paid or claimed by Relator or his counsel.

4. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Defendant's full payment of the Settlement Amount, the United States releases Defendant together with its current and former direct and indirect parent corporations and limited liability companies (the "Parents"); its and their affiliates, direct and indirect subsidiaries, brother and sister companies, and divisions; and its and their respective current and former owners, officers, directors, and employees; and the predecessors, successors, transferees, and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any

statutory provision creating a cause of action for civil damages or civil penalties which the Civil Division of the Department of Justice has actual or present authority to assert and compromise under 28 C.F.R. Pt. 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 8 below, and conditioned upon Defendant's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Defendant together with its Parents; its and their affiliates, direct and indirect subsidiaries, brother and sister companies, divisions, and limited liability companies and any other legal entities directly or indirectly controlled by any of the Parents; and its and their respective current and former owners, officers, directors, employees, agents, and attorneys; and the predecessors, successors, transferees and assigns of any of them from any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from any and all claims for relief, actions, rights, causes of action, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character, or nature whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that they, their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

6. **OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action against Astellas Pharma US, Inc. and/or its officers, directors, and employees from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).**

7. **OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against Astellas Pharma US, Inc. from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).**

8. **Notwithstanding the release given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:**

- a. **Any liability arising under Title 26, U.S. Code (Internal Revenue Code);**
- b. **Any criminal liability;**
- c. **Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;**
- d. **Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;**
- e. **Any liability based upon obligations created by this Agreement;**
- f. **Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;**

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

10. Defendant waives and shall not assert any defenses Defendant may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

11. Defendant fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees,

costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), FEHBP carrier or payer, or any state payer, related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare contractor, FEHBP carrier or payer, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

13. Defendant agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendant, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Defendant's investigation, defense, and corrective actions taken in response to the United States' audit(s) and civil investigation(s)

in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Defendant makes to the United States pursuant to this Agreement and any payments that Defendant may make to Relator, including costs and attorneys' fees; and

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. **Future Treatment of Unallowable Costs:** Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendant or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. **Treatment of Unallowable Costs Previously Submitted for Payment:** Defendant further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid

program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendant or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Defendant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendant or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. Defendant agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1(a), above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice to the United States and Relator as to the Covered Conduct, and with prejudice to the Relator and without prejudice to the United States as to all other claims.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Pennsylvania. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties.

This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Defendant's successors, transferees, heirs, and assigns.


24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

25. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4/2/14

BY: 
CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
ZANE DAVID MEMEGER
United States Attorney
Eastern District of Pennsylvania

DATED: _____

BY: _____
MARGARET L. HUTCHINSON
Assistant United States Attorney
Chief, Civil Division
Eastern District of Pennsylvania

DATED: _____

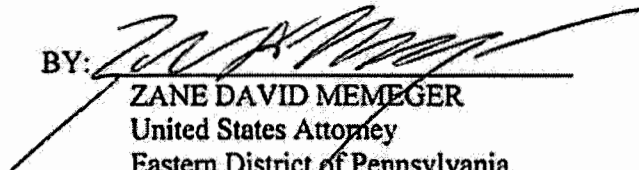
BY: _____
SUSAN R. BECKER
Assistant United States Attorney
United States Attorney's Office
for the Eastern District of Pennsylvania

THE UNITED STATES OF AMERICA


DATED: _____

BY: _____
CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

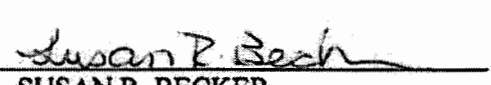
DATED: 4/8/14

BY: 
ZANE DAVID MEMEGER
United States Attorney
Eastern District of Pennsylvania

DATED: 4/8/14

BY: 
MARGARET L. HUTCHINSON
Assistant United States Attorney
Chief, Civil Division
Eastern District of Pennsylvania

DATED: 4/8/14

BY: 
SUSAN R. BECKER
Assistant United States Attorney
United States Attorney's Office
for the Eastern District of Pennsylvania

DATED: _____

BY: _____

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: **APR - 3 2014**

BY:  _____

LLOYD V. WILLIAMS
Deputy Director
for Federal Employee Insurance Operations
United States Office of
Personnel Management

DATED: 4/7/14

BY: Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

DATED: _____

BY: _____
LLOYD V. WILLIAMS
Deputy Director
for Federal Employee Insurance Operations
United States Office of
Personnel Management

ASTELLAS PHARMA US, INC - DEFENDANT

DATED: 4/3/2014

BY: Linda F. Friedman
LINDA F. FRIEDMAN
Astellas Pharma US, Inc.
Secretary

DATED: 4/3/2014


BY: Thomas M. Gallagher
THOMAS M. GALLAGHER
Pepper Hamilton LLP
Counsel for Defendant Astellas Pharma US, Inc.

FRANK SMITH - RELATOR

DATED: 4/4/14

BY: 
FRANK SMITH
Relator

DATED: 4/4/14

BY: 
STEPHEN J. SELLER
Sheller, P.C.
Counsel for Relator Frank Smith

DATED: 4/9/14

BY: 
JOSEPH TRAUTWEIN, ESQUIRE
Joseph Trautwein & Associates, LLC
Counsel for Relator Frank Smith